K111572(pg 1/3)

AUG 2 9 2011

510(k) Summary

Date: August the 23td, 2011

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Contact person: Caroline GELLY
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Date prepared: August the 23td, 2011

Trade name: NOVAE® Dual Mobility Acetabular Cup

Common name: Total hip prosthesis – Acetabular component

Classification name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO/MEH)

Device description
The NOVAE® Dual Mobility Acetabular Cup is composed of a metallic shell fixed in the acetabulum and a polyethylene liner.

Cemented metallic shell:
- **NOVAE STICK:** the cemented metallic shell is made of stainless steel according to ISO 5832-1:2007. The outer surface is sandblasted and presents macro-volumes to augment contact between the implant and the cement. The inner surface is highly polished.

Cementless metallic shell:
The cementless metallic shell is made of stainless steel according to ISO 5832-1:2007 and is coated with a CP titanium and hydroxyapatite plasma spray (double layer coating) on the outer surface and is highly polished on the inner surface.

Three cementless metal-backs are available:
- **SUNFIT TH**: the SUNFIT TH version is available without the pegs and screw, and is a press fit only.
- **NOVAE E TH**: the NOVAE E TH has 3 fixation points (2 divergent pegs towards the pubis and ischium and 1 cortical screw through a flange towards the ilium).
- **COPTOS TH**: the COPTOS TH has 5 fixation points (2 divergent pegs towards the pubis and ischium, cortical screws through 2 flanges towards the ilium and 1 foramen hook).

Liner:
The liner is made of Ultra-High-Molecular-Weight Polyethylene according to ISO 5834-2:2006. The liner is mobile (free) in the metallic shell and retained on the prosthetic femoral head. Liners can be used with ∅22,2 or 28 mm prosthetic femoral heads.

Pegs and cortical screws:
When applicable, primary fixation can be reinforced by impacted pegs and self tapping cortical screws made of stainless steel according to ISO 5832-1:2007.

Substantial equivalence claimed to predicate devices
NOVAE® Dual Mobility Acetabular Cup is substantially equivalent to the POLARCUP® dual mobility system (K070278, PLUS Orthopedics) in terms of intended use, design, range of sizes, materials used, mechanical safety and performances, the Restoration™ ADM system (K072020, Stryker) in terms of intended use, design and metal-back coating and the Tri-Polar system and RingLoc® + modular acetabular shell (K991990, BIOMET) in terms of intended use, design and range of sizes.

Device	**NOVAE® Dual Mobility Acetabular Cup**	**POLARCUP® dual mobility system**	**Restoration™ ADM System**	**Tri-Polar system and RingLoc® + modular acetabular shell**
510(k) number	/	K070278	K072020	K991990
Intended use				
Total hip replacement	Yes	Yes	Yes	Yes
Cementless/ cemented	Yes/Yes	Yes/No	Yes/No	Yes/No
Primary/ Revision	Yes/Yes	Yes/Yes	Yes/No	Yes/Yes
Design				
Dual mobility	Yes	Yes	Yes	Yes
Metal-back and a mobile liner	Yes	Yes	Yes	No (bipolar head + acetabular cup)
Screws	Cortical	Cortical	No screws	Screws
Pegs	Grooved	Grooved	No pegs	No pegs
Liner is retained on the head	Yes	Yes	Yes	Yes
Materials				
Metal-back	Stainless steel (ISO 5832-1:2007)	High nitrogen stainless steel (ISO 5832-9:1992)	Wrought Cobalt Chromium alloy	Titanium alloy
Metal-back coating	CP titanium and HA	CP titanium	CP titanium and HA	Titanium alloy
Liner	UHMWPE	UHMWPE	UHMWPE	Polyethylene
Pegs and Screws	Stainless steel	Stainless	Not applicable	Unknown

Intended use

NOVAE® Dual mobility Acetabular Cup is indicated for total hip replacement, which includes:

- Osteoarthritis
- Femoral neck fracture
- Dislocation risk
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits

SUNFIT TH, NOVAE E TH and COPTOS TH are intended for press-fit use and NOVAE STICK is indicated for cemented use

Non-clinical Test Summary

The following tests were conducted:

- Dimensional analysis (acceptance criteria was met)
- Uncemented metal-back push-out force (acceptance criteria was met)
- Head insertion force and Head Pull-Out testing (acceptance criteria was met)
- Head lever out force (acceptance criteria was met)
- Number of bending cycles to flange fracture (acceptance criteria was met)
- Characterization of CP titanium and HA plasma spray (acceptance criteria was met)
- Range Of Motion Analysis (acceptance criteria was met)
- Wear Analysis (acceptance criteria was met)

Clinical Test Summary

No clinical studies were performed

Conclusions Nonclinical and Clinical

The NOVAE® dual mobility acetabular cup is substantially equivalent to the predicate devices in terms of indications for use, design, material, function and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SERF
% Mr. J.D. Webb
Orthomedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

AUG 29 2011

Re: K111572
Trade/Device Name: NOVAE® Dual Mobility Acetabular Cup
Regulation Number: 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: May 5, 2011
Received: June 6, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): / K111572 (pg 1/1)

Device Name: NOVAE® Dual Mobility Acetabular Cup

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Mellerm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111572